DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 18-343/S-073

APR. 20 1999

Apothecon Inc.
A Bristol-Myers Squibb Company
Attention: Ms. Liz Sagan-Graves
P.O. Box 4500
Princeton, NJ 08543-4500

Dear Ms. Sagan-Graves:

Please refer to your supplemental new drug application dated January 8, 1998, received January 13, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Capoten (captopril) 12.5, 25, 50 and 100 mg Tablets.

We acknowledge receipt of your submission dated March 3, 1999. Your submission of March 3, 1999 constituted a complete response to our February 13, 1998 action letter.

This supplemental new drug application provides for final printed labeling revised as follows:

The SQUIBB logo has been changed to the Bristol-Myers Squibb Company logo.

"CAUTION: Federal law prohibits dispensing without prescription." has been changed to "Rx only."

Throughout the labeling, "(captopril tablets)" has been either replaced with "(captopril tablets, USP)" or deleted."(captopril tablets, USP)" is used at least once per column, and other uses have been deleted..

PRECAUTIONS, Drug Interactions: The following has been added to the end of this subsection:

Cardiac Glycosides: In a study of young healthy male subjects no evidence of a direct pharmacokinetic captopril-digoxin interaction could be found.

Loop Diuretics: Furosemide administered concurrently with captopril does not alter the pharmacokinetics of captopril in renally impaired hypertensive patients.

Allopurinol: In a study of healthy male volunteers no significant pharmacokinetic interaction occurred when captopril and allopurinol were administered concomitantly for 6 days.

HOW SUPPLIED:

"CAPOTEN (captopril tablets, USP)" has been added at the beginning of this section.

Storage: The first sentence has been revised to add "(30° C)" at the end.

The company name and address has been changed to
"Bristol-Myers Squibb Company
Princeton, NJ 08543 USA"

In addition, minor editorial revisions have been made throughout the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your March 3, 1999 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 3 14.80 and 314.81.

If you have any questions, please contact:

Ms. Kathleen Bongiovanni
Regulatory Health Project Manager
(301) 594-5334

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research